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## **Cultures and Strategies in the Regulation of Nanotechnology in Germany, Austria, Switzer- land and the European Union**

This interdisciplinary, social scientific analysis of the regulatory discourse on nanotechnology in the three German-speaking countries Germany, Austria and Switzerland and in the EU between 2000 and 2013, has shown three distinct phases, characterised by shifts in the configuration of actors and in the thematic scope from nanotechnology to nano-materials. Compared to modes of governance based on traditional statutory law, modes of governance based on less binding forms of soft law and self-regulation (like codes of conduct, guidelines and certification systems) and new modes of governance, (like assessment studies, risk management frameworks as well as participatory and cooperative forms of communication and negotiation) have gained importance. Despite some similarities two different cul-

tures in governing nanotechnology can be distinguished: a product<sup>1</sup>-oriented culture in statutory regulations and a risk-based culture in applying soft law based on new modes of governance. In addition, the different regulatory cultures have led to four strategic approaches: modes of governance mainly based on hard law and soft law at the EU level, modes of governance mainly based on cooperative and self-regulatory approaches in Germany, cooperative governance approaches in Austria and modes of governance mainly based on self-regulatory and soft law approaches in Switzerland.

**Key words:** nanotechnology, regulatory culture, governance, Austria, Germany, Switzerland, EU.

## 1 Introduction

Discourses on regulatory implications of nanotechnology emerged in direct response to the launch of new research and development support programmes and initiatives in almost every Western industrialized nation in the early 2000's. This early start of regulatory dis-

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<sup>1</sup> When speaking about products the article is also referring to substances.

courses, compared to previous technological developments, was associated with intensive efforts of assessment activities. These have almost started concurrently with the establishment of national research initiatives (Kaiser, et al. 2009). These mainly consisted of traditional technology assessment (e.g. Paschen, et al. 2004; RS&RAE 2004), of toxicological studies (e.g. Borm & Kreyling 2004; Donaldson, et al. 2004; Kreyling, et al. 2002; Oberdörster 2001) and of ethical, legal and social implication (ELSI) and cultural studies analyses.<sup>2</sup> Regulatory discourses however, did not only develop in almost every country involved in research and development of nanotechnologies but also on the supranational level of the European Union (EU) and in international organisations, like the OECD. Besides modes of governance based on *statutory law* – referred to as ‘*hard law*’ and such based on less binding and more voluntary

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<sup>2</sup> On ELSI and cultural studies analyses see e.g. (Baird, et al. 2004; Bergeson & Auerbach 2004; Cobb & Macoubrie 2004; Coenen 2004; Fogelberg & Glimell 2003; Grove-White, et al. 2004; Grunwald 2004; Hayles 2004; Hilgartner & Thurs 2005; Khushf 2004; Kulinowski 2004; Lewenstein & Scheufele 2005; López 2004; Lösch 2004; Mehta 2004; Milburn 2004; Nordmann, et al. 2004; Schummer 2004).

measures, referred to as ‘*soft law*’<sup>3</sup> – lying in the jurisdiction of parliaments, governments and administrations, various actors in the field of nanotechnology have developed modes of governance based on self-regulation and informal, distributed and participative approaches – referred to as ‘*new governance*’ (Peters 2011; Peters & Pagotto 2006). As e.g. the current course in the EU shows, these two modes can coexist (e.g. Eberlein & Kerwer 2004; Scott & Trubek 2002). In political discourses and in science policy related decision-making a shift from “governmental forms of regulation” to “governance” was described (Rhodes 1997). Depending on the analytical perspective, literature refers to a “governance turn” (Borràs 2008; Rose & Miller 1992), a „deliberative turn” (Hagendijk & Irwin 2006), a „qualitative turn” (Kearnes 2009) or to a “turn from modernist to post-modernist forms of statecraft” (Gottweis & Petersen 2008), and with regard to science and technology policy to a „new governance of science” (Gibbons, et al. 1994; Irwin 2006; Jasanoff 2005; Weingart 2001). Furthermore, the rise of a ‘new governance

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<sup>3</sup> Such voluntary approaches consist of aspects like risk assessment schemes, various codes of conduct and the establishment of advisory boards and committees for dialogue. See e.g. Hodge,

turn' has been described (e.g. de Búrca & Scott 2006; Lyall & Tait 2005). 'New governance' stands for informal regulatory approaches, like technology and risk assessment, risk management frameworks as well as participatory and cooperative forms of communication and negotiation, combined with forms of self-regulation (e.g. Eberlein & Kerwer 2004; Scott & Trubek 2002).

Against this background, this interdisciplinary, social scientific study, which is neither a legal nor a sociological analysis, has evaluated regulatory discourses on nanotechnology in the three European countries Germany, Austria (both EU members) and Switzerland (non-EU member) as well as at the EU level since 2000. This comparative study, which is neither a legal nor a sociological analysis, has followed a discourse analytical approach and has used methods from both fields, like legal and document analysis, interviews and participant observation of the authors in events and panels of the regulatory discourse. The analysis has focused on discourses, carried out within governmental institutions, like the parliament and administration as well as government external discourses. It further studied

the related modes of governance based on hard law, on soft law as well as new modes of governance, including self-regulatory approaches of non-governmental organisations and the private sector, like risk management frameworks, various codes of conduct, certification systems, safety guidelines and manuals of manufacturers and industry associations. Moreover, in the context of new governance also participatory approaches like stakeholder dialogues and citizen conferences have been analysed as well as private regulatory assessment reports and reports initiated by government on the impact of technology, opportunities, risks, and innovation. Documents analysed consisted of legislative texts, regulations, council minutes, printed materials, legal opinions, documentations of informal approaches, reports made by officials and other governmental organisations and commissions as well as reports from external actors, like documentations of self-regulatory approaches, dialogue protocols etc.

The comparison is based on a qualitative science and technology studies (STS) driven research approach, using the concept of *regulatory culture* (Brickman, et al. 1985; Jasanoff 1986; Jasanoff 1987;

Jasanoff 1995; Jasanoff 1997; Jasanoff 2005, 21 ff.). The categories like *representation*, *participation* and *negotiation*, developed by Jasanoff (2005, 280-287) for a comparison of political cultures, have been further specified and adapted for the needs of this study. It has become clear that for the analysis of a regulatory discourse, aiming at comparing regulatory cultures, *discursive* elements as well as *practices* of regulation need to be analysed. This has led to the three analytical categories: *issues*, *actors* and *practices* and the following analytical framework for the comparison:

- *Issues*: Which subjects, topics, contents and themes are discussed in the regulatory discourse on nanotechnology?
- *Actors*: Who participates in regulatory discourses; who is involved in governing nanotechnology and who is not?
- *Practices*: What modes of governance and what kind of policy tools are used in governing nanotechnology, how are they implemented, where are they included, and how are they further developed?

However, neither regulatory cultures are taken for granted nor issues, actors and practices are considered as being stable and separat-

ed entities. Rather, regulatory discourses and the social order are framed as being coproduced, as issues and practices emerge in relation to actors and vice versa (Jasanoff 2004). In this notion, the analysis of regulatory cultures looks at specific discourses, measures or modes of governance that shape the interaction between actors, issues and practices in specific ways.

Section 2 provides a chronological overview on three phases of the regulatory discourse of nanotechnology between 2000 and 2013. Here, specific measures and modes of governance are discussed that have shaped the regulatory cultures of nanotechnology in the three countries and the European Union.<sup>4</sup> Based on this overview, section 3 discusses those specific measures and modes of governance according to the three categories: issues, actors and practices. Section 4 focuses on the temporal dimension of the regulatory discourse based on the three categories in three phases. Here, the shift of the

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<sup>4</sup> This analysis focuses selected initiatives and measures with regard to the governance of nanotechnology. Those were selected in an exemplary way according to their documentation in related literature, and to whether they were observed and mentioned in interviews and participant observation, the authors conducted in the three countries. Therefore, the discussed measures have rather served as examples or cases based on which the argument is built on than providing a comprehensive list of all relevant governance measures. This has never been the aim of the authors. Therefore, the qualitative approach, selected for this study leads to the consequence that some measures are analysed while others are missing.



topics and the configuration of actors within the three phases is outlined as well as how legislation, self-regulatory and informal approaches have been established. The final section 5, presents the categorization of the observed issues, actors and practices into two regulatory cultures with different culture-specific strategies.

## **2 Three phases in the regulatory discourse from 2000–2013**

This section gives a chronological overview on the regulatory discourse on nanotechnology in Germany, Austria and Switzerland as well as in the EU between 2000 and 2013. This discourse can be distinguished in three sometimes overlapping but mostly separable phases: an early phase of a broad thematic discussion of nanotechnology by a relatively small range of participants, a middle phase of intensive and broad thematic discourse with a wide range of actors and a late phase with a determined thematic emphasis on nano-materials and a simultaneously extended range of participants.

The study has further showed that at the beginning of the discourse, technology assessment in all analysed countries played an important

role and thus chances, risks and need for research have been centrally negotiated. The discourse became more intensive in a phase of broadened participatory occasions, which included stakeholders as well as civil society. At the end of our analysis, the regulatory discourse decreased and narrowed its thematic scope on environment, health and safety issues (EHS) of nano-materials and became mainly conducted by the related social and political actors.

### ***2.1 The early phase: Research, innovation and assessment***

In Germany and in Switzerland the regulatory discourse on nanotechnology emerged in the years 2000 and 2001 and intensified in 2005-2007. Both countries have come up with parliamentary interventions and debates. The first issues within the German Bundestag focused on the state and development of nanotechnology, its opportunities, risks and specific scientific guidelines. Further issues, discussed in the Bundestag, covered nanotechnology research and development, nano-specific regulation in the protection of consumers,

health, data and the environment.<sup>5</sup> Furthermore, the research policy administrations faced a phase of orientation in which the definition of the research area as well as the precise formulation and financial funding of support programmes were still fairly open.<sup>6</sup> The Swiss Parliament's National Council discussed and rejected the set-up of an advisory board on new technologies with the aim of covering political and ethical questions, chances, risks, social implications, national and international cooperation as well as military applications.<sup>7</sup>

In 2002 the German Federal Ministry of Education and Research (BMBF) published a position paper, showing the status of an early “action plan” without explicitly using this term (BMBF 2002). In 2004 the BMBF published another position paper, which was—although the title did once again not indicate it—considered as the

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<sup>5</sup> See also printed matters (Drucksache 14/5443 2001; Drucksache 15/2650 2004; Drucksache 15/3051 2004; Drucksache 15/3754 2004) and plenary protocol (PP15/148 2004) of the German Parliament.

<sup>6</sup> On that, see e.g. (BMBF 2002; BMBF 2004a; BMBF 2004b).

<sup>7</sup> See Swiss National Council postulate submitted by National Councillor Hans Widmer (SP) of 14.12.2000, in which he requests the Swiss Federal Council to establish a council for new technologies and Swiss National Council request by National Councillor Barbara Haering (SP) from 01.12.2004 to the Swiss Federal Council regarding potential environmental and health risks from military uses of nanotechnology ([http://www.parlament.ch/d/suche/seiten/geschaefte.aspx?gesch\\_id=20003686](http://www.parlament.ch/d/suche/seiten/geschaefte.aspx?gesch_id=20003686) /visited 04.06.2014).

first nanotechnology action plan of Germany (BMBF 2004a).<sup>8</sup> Herein, the BMBF stated that there was no need for a separate regulation of nanotechnology (BMBF 2004b).

From 2003 onwards the first publicly funded research policy analyses and technology assessment (TA) studies (e.g. Baumgartner, et al. 2003; Paschen, et al. 2004)<sup>9</sup> were released in Germany and Switzerland. Furthermore, private actors began to publish assessment studies (e.g. MunichRe 2002; Swiss Re 2004). The focus of the German publicly commissioned studies was on TA (Paschen, et al. 2004), financed by the Parliament, and on innovation and technology analyses with the focus on economic potential (Luther, et al. 2004). Further studies covering sustainability effects and health were both supported by the BMBF (AGIT 2004; Haum, et al. 2004). In addition, a research policy position paper on nanotechnology analysed its market potential and stressed the strategic need to exploit it for the German economy (BMBF 2004a).

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<sup>8</sup> In Germany the term 'action plan' was for the first time explicitly used in the BMBF (2007) publication.

<sup>9</sup> The studies were financed by the Federal Ministry of the Environment (BMU) respectively the Swiss organisation for technology assessment TA Swiss.

Another study, funded from public resources, focused on nano-materials, their definitions and scientific development and was conducted by the TA institution *European Academy for Research and Assessment of Consequences of Scientific and Technical Developments* (Schmid, et al. 2003).

In Switzerland, the national Centre for Technology Assessment (TA Swiss) issued a report on nanotechnology in medicine (Baumgartner, et al. 2003). Private studies like the one of the Swiss reinsurance company Swiss Re and of the think tank International Risk Governance Council (IRGC) analysed nanoscience and nanotechnology from a wide thematic range as well as nano-materials and their potential toxicity (e.g. IRGC 2006; Swiss Re 2004).

In Germany, the Chemical Industry Association (VCI) and the multinational chemical company BASF developed a code of conduct for safe handling of nano-materials at the workplace (BASF 2006). While many of these early studies showed a wide range of visions, applications, implications, hazards and risks, the potential adverse effects of nano-materials on health and environment were paid particular attention.

At the EU level the regulatory discourse started when the EU Commission published a nanotechnology strategy in 2004 (Commission 2004) and released an action plan in 2005 (Commission 2005). In those communications, the EU Commission assessed nanotechnology as a core research and development field and put emphasis in the technology's potential for international competition and economic leadership. The EU Commission further argued that the existing regulatory framework was sufficient in covering the hazards and risks and that any regulation must be embedded into the existing legal framework. Furthermore, the Commission advertised to comprehensively review the adequacy of the existing law for covering nanotechnology (COM 2004; COM 2005).<sup>10</sup>

Discourses in this phase were mainly conducted in promise and expectation-oriented innovation rhetoric. They mainly focused nanomaterials and nano-phenomena and already covered a wide range of issues. This phase was also framed by futuristic discourses and 'speculative'—as the scientific community sometimes called them—

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<sup>10</sup> For this and further analysis see Eisenberger, Nentwich, Fiedeler, Gazsó & Simkó (2010) 'Nano Regulation in the European Union', in ITA (ed), NanoTrust-Dossiers (Wien: Institut für

future scenarios of nanotechnology (cf. e.g. also Grunwald 2006; Lösch 2006; Nordmann 2006). Particularly in the U.S. such visions played an important role in attracting the initial focus of the science policy discourse on nanotechnology and in the allocation of public funding in the nanotechnology field around the early 2000s (e.g. Schummer 2004; Selin 2007). They were initially taken up in other countries, like in the parliamentary discourses in Germany and Switzerland (see above) and particularly influenced the first German nanotechnology strategy (BMBF 2002). Moreover, it is difficult to make statements about the role that the early, visionary debates about nanotechnologies played for future regulatory strategies. We can only speculate on the role of visions or ‘speculative ethics’ in the nanotechnology discourse. Nanotechnology might have been put on the political agenda because the visions about molecular nanotechnologies and its potential impacts have created substantial media awareness, not least in quality newspapers.<sup>11</sup> The visionary discourse

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Technikfolgen-Abschätzung (ITA), [http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017\\_en.pdf](http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017_en.pdf) ).

<sup>11</sup> E.g. the Frankfurter Allgemeine Zeitung, one of the most influential daily newspapers in Germany has published a series of articles by futurists, scientists and engineers about nanofutures, which was widely discussed in political circles.

might also have pushed groups that were more interested in allocating funding for ‘conventional nanotechnologies’ to develop counter-narratives, highlighting the everyday use and more current opportunities of nanotechnologies.<sup>12</sup> The early nanotechnology debates addressed more prominently ethical issues like distributional justice or the role of science in economic policy, topics that almost entirely disappeared from later nanotechnology discourses (see e.g. Lösch 2010). Furthermore the visionary discourse attracted the interest of German environmental organisations. In discussing the importance of nanotechnologies as a future topic for their work, they considered several visions as too speculative. In parallel they discovered the potential of other visions and found parallels and differences between nanomaterials and chemicals policy problems. Chemicals policy, in turn, is a core area of activity (and expertise) for civil society organisations mainly in Germany. The reframing of a visionary nanotechnology as more realistic nanomaterials resulted in benefiting both: The influential proponents of nanotechnology research funding, who

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<sup>12</sup> This led e.g. later to the ‘nano for ...’ strategies of the German Federal Ministry of Education and Research (BMBF).



were mainly based in academia and industry, and its critics, who came mostly out of environmental organisations. In this notion, nanotechnology became a development that was related to the broader political agenda of dissident organisations.

As it is shown in the next section, visions lost their importance in the middle phase of the regulatory discourse. They e.g. did not play a significant role in the nanotechnology action plans and implementation reports of the EU, Switzerland, Germany and Austria anymore that emerged in 2004 and later (e.g. BMBF 2007; CH-Bundesrat 2008; COM 2007).

## ***2.2 The middle phase: Intensifying discourses in the context of participation***

In a relatively short phase between 2005 and 2007 the regulatory discourses in Germany and Switzerland became considerable intensive. This was also the time, when the discourses started in Austria. In this phase, besides the ongoing research policy issues, the regulatory discourses in all the analysed countries started to focus on favourable applications of nanotechnology for human health and the

environment. Particularly in Germany, the research policy discourses were connected with a concentration on nanotechnology research and development on applications, considered to be particularly relevant for economy and society, like nano-electronics, automotive manufacturing, optical technologies and life sciences.

Comparable to the early phase in Germany and Switzerland, the regulatory discourses in Austria began with a technology assessment study. While in Austria nanotechnology implications were discussed in a wide thematic range, in the two other countries the discourses started to focus more on concrete applications and implications like environmental, health and safety (EHS) implications of nanomaterials. In this phase, the visions almost entirely disappeared from the regulatory discourse, what Löscher (2010) calls a 'defuturization'.

In Germany, the involved actors particularly consisted of the federal institutions in charge of economic and innovation policies. Since 2006, institutions with protective functions (environment, health, employment, and consumer protection) have increasingly entered into public and regulatory discourses. Thus, all parliamentary groups in the Bundestag, the federal government as a whole, several federal

ministries (in particular the Federal Ministry of Education and Research BMBF and the federal Environment Ministry BMU) as well as higher federal authorities and departmental research institutes like the Federal Environment Agency (UBA), the Federal Institute for Occupational Safety and Health (BAuA) and the Federal Institute for Risk Assessment (BfR) became involved in the discourses. Further actors consisted of environment and consumer protection agencies like the environmental association BUND, the Federation of German Consumer Organisations (vzbv) as well as industry associations like the Association of the Chemical Industry (VCI) and the German Federation of Food Law and Food Science (BLL). In this phase, the German Government funded governance oriented, EHS-related research studies. In this context, e.g. the Society for Institutional Analysis (sofia) Darmstadt and the Ökoinstitut Freiburg published a legal opinion (Führ et al. 2006) and the Karlsruhe Institute for Technology Assessment and Systems Analysis (ITAS) issued several studies (e.g. Fleischer, et al. 2004; Grunwald 2004; Grunwald 2006). In addition, a number of research programmes in the fields of nanotoxicology, standardization and instrumentation with public and pri-

vate participation were initiated and leading scientists regularly took part in the evolving risk discourses. In parallel, the multinational corporation BASF launched a dialogue forum on EHS issues of nano-materials in Germany. The two sessions, organized so far, aimed at exchanging nanotechnology issues with trade unions, civil society organisations, scientists and representatives of other companies (suppliers and customers) and resulted in the formulation of two individual position papers (BASF 2009; BASF 2011). In addition, BASF developed a workplace safety guideline for nano-materials in 2006 (BASF 2006). Next to manufacturers also the German Association of Chemical Industries (VCI) published positions and recommendations in handling nano-materials (VCI 2006) and developed a guideline for workplace safety together with the Federal Institute for Occupational Safety and Health (BAuA & VCI 2007). They updated their guidelines in 2012 (BAuA & VCI 2012). Compared to the other analysed countries, the German manufacturing industry is particularly active, which has influenced both, the development of regulatory discourse and some governance choices of the German government, like e.g. that the Ministry of the Environment

did not develop a voluntary reporting scheme as it has been the case in the U.S. and the UK.

In Germany and Switzerland first participatory processes were carried out. While the German Federal Ministry for the Environment (BMU) initiated a stakeholder dialogue on environmental protection and occupational health and safety, TA Swiss carried out three focus group hearings with the public and one involving stakeholder groups on nanotechnology in a broad thematic scope (Cerutti 2006; Rey 2006). The German BMU stakeholder dialogue, initiated by an initiative of the former Federal Minister of the Environment, was turned into the *NanoKommission* in 2006.

Then, the German NanoKommission was introduced by the Federal Government as the national dialogue forum. Its administration was issued to the Environment Ministry (BMU). Although perceived as a single entity, the “NanoKommission” actually consisted of two consecutive commissions with partly different memberships and different key areas of activity (Kurath, et al. 2014). The first NanoKommission (2006–2008) comprised 15 people representing science, economy, politics and NGOs and was supported by three working

groups (each approximately comprising 20 members, from all active stakeholder groups) focusing on issues such as “chances for environment and health”, “risks and safety research” as well as “guidelines for a responsible handling of nano-materials”. This phase was followed almost seamlessly by the second working period from 2009–2011, described either as “second phase of NanoKommission” or as “the second NanoKommission” (Kurath, et al. 2014).

In 2006, the German Bundestag particularly discussed issues, like benefits and risks, environment and health protection, research policy, and food.<sup>13</sup> In August 2006 three higher federal authorities the Environment Agency (UBA), the Institute for Occupational Safety and Health (BAuA) and the Institute for Risk Assessment (BfR) published a joint research strategy (BMU, et al. 2005). In the same year, the UBA published a background paper on opportunities and risks of nanotechnology for human health and the environment (UBA 2006) and the Federal Ministry of Education and Research (BMBF) developed the NanoCare information platform on synthetic

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<sup>13</sup> Cf. printed matters (Drucksache 16/2150 2006; Drucksache 16/2322 2006) of the German Parliament.

nano-particles.<sup>14</sup> Also environmental organizations published reports on issues, like environment and health protection (e.g. BUND 2006; BUND 2007). Furthermore, in November 2006 the BMBF as lead ministry, presented the “Nano-Initiative – Action Plan 2010” within the framework of the HighTech-Strategy of the German Federal Government (BMBF 2007). In this initiative, the BMBF described the requirements of the market success of a German “knowledge lead” in various areas of nanotechnology and presents an expanded and cross-departmental action frame. It further specified the aim of the German government to establish a national dialogue board: the NanoKommission (see above).

In Switzerland the regulatory discourses were characterised by several discussions in the Parliament, covering issues like public health and environment, the need for a regulatory framework, support of innovation as well as the call for a national research funding program for an in-depth analysis of potential risks and benefits of syn-

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<sup>14</sup> Meanwhile transferred into the follow-up project DaNA [www.nanopartikel.info/cms/Projekte/NanoCare](http://www.nanopartikel.info/cms/Projekte/NanoCare) (viewed, 4.6.2013).

thetic nano-materials and nano-technological applications (reference on own research).

In Austria the regulatory discourses started in 2006 with the publication of a TA report on accompanying measures in Nanotechnology, solicited by the Federal Ministry for Transport, Innovation and Technology (BMVIT) and conducted by the Institute for Technology Assessment (ITA) of the Austrian Academy of Sciences (ITA 2006). The report dealt with issues relating to the state of knowledge, regulation, self-regulatory approaches, voluntary agreements and best-practice initiatives, which have been recommended in particular for the field of chemicals. In parallel, the study “Nano-Health – health risks of nanotechnology” funded by the Federal Ministry of Economy (BMWA) and the Zukunftsfonds Steiermark, was published by BioNanoNet Styria (Nentwich 2014). Both projects developed joint recommendations to the government to adapt existing regulations in particular those in the fields of chemicals legislation, product liability, insurance and consumer protection, and if necessary to develop a new regulatory framework. Furthermore the authors of those studies suggested to initiate—comparable to other



countries—EHS and ELSI research activities on nanotechnology (cf. ITA 2006).

### ***2.3 The late phase: Flattening of discourses and focusing on materials, environmental, health and safety issues***

Subsequently, the regulatory discourses in Germany and Switzerland decreased, however, remained on a significantly higher level than before 2006 and expanded in Austria. In all the analysed countries as well as in the EU this phase showed once again an expansion of the range of actors with a simultaneously comprehensive thematic focus on *nano-materials*. The discourses focused on issues, like the application of nano-materials in consumer products, environmental, health and safety (EHS) and related regulatory issues. The range of issues narrowed from thematically extensive negotiations on nanosciences and nanotechnologies as a whole to a rather restricted and almost exclusive concentration on nano-materials.

**In Germany,** parliamentary interventions and debates still played a major role. Thus the German Bundestag discussed issues like regulation, precautionary principle, risks, occupational health and safety,

consumer protection, responsible approach, promotion of research, development and innovation, environment and health protection, nano-silver, reporting obligations, product register, labelling requirements, chemical regulation, hazardous substances, action plan as well as research policy and accompanying research.<sup>15</sup> The (first) NanoKommission of the Federal Government published its final report in 2008 (NanoKommission 2008). The report developed a ‘Declaration of Principles for Responsible Use of Nano-materials’ aiming at the participating stakeholders to consider this declaration like a code of conduct for the stakeholders participating in the NanoDialog. The subsequently initiated second NanoKommission was expanded to 16 people and slightly modified: instead of the BDI (the umbrella Association of German Industry) and representatives of the hard sciences, members from churches, the Ministry of Consumer Protection as well as Lawyers have become included. The working structure remained similar and the work of the commission was supported by four thematic groups (“Monitor the implementation of the

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<sup>15</sup> On these issues see e.g. printed matters (Drucksache 16/6337 2007; Drucksache 17/3689 2010; Drucksache 17/8158 2011; Drucksache 17/9569 2012) of the German Parliament.

principle“, “Development of a technical guidance for a survey and comparison of benefit and risk aspects of nano-products“, “Examination of regulations of nano-materials and nano-products“ and “Criteria on a preliminary assessment of nano-materials with regard to their effects on human health and the environment” as well as an additional working group “Sustainable nanotechnologies – Green Nano”). The working groups consisted of 20 to 25 members each. The second NanoKommission put a stronger thematic focus on regulatory issues, which narrowed the possibilities of generating consensus, particularly in the thematic groups 1 and 3. In 2011, the second NanoKommission published its final report, which mainly specifies on a better implementation of the five principles for a responsible handling of nano-materials (BMU 2008). Furthermore the report provides the basis for a guideline to oppose benefits and risks of nano-products and criteria to assess nano-materials with regard to their environmental, health and safety implications. It further consists of an opinion on the regulatory need and recommends to develop a guideline on green nanotechnologies ‘Green Nano’ (BMU 2011b). Both reports showed that governance strategies emerging

from the NanoKommission rather focused on risk management approaches than on soft or hard law.

The Federal Environmental Agency published an updated edition of the background paper of 2006 (UBA 2009). Further governmental and non-governmental organisations such as the Federation for Food Law and Food Science and the Federation of German Consumer Organisations as well as the Federal Government discussed issues like food and consumer protection.<sup>16</sup>

Regulatory issues were discussed in a legal opinion commissioned by the Federal Ministry of Environment (BMU) and composed by the Ökoinstitut Freiburg and the Society for Institutional Analysis Darmstadt, published in December 2006 (Nentwich 2013). This report focussed potential adaptations of the existing legal framework to the needs of nanotechnology. In particular this report suggested to adapt the European chemical regulation REACH to nano-materials and to explicitly mention those, to reduce the product volume from 1 ton per year for the registration of nano-materials and to develop

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<sup>16</sup> See the following policy documents and printed matter of the German Parliament (BLL 2009; Drucksache 16/9163 2008; vzbv 2009).

specific test and monitoring approaches. Furthermore, the report also suggested more voluntary governance forms, like encouraging self-regulation and work on standardisation (ibid.). The suggestion to adapt the chemical regulation was also taken up in reports by the Federal Government and by consumer groups, here in particular with regard to consumer protection.<sup>17</sup> The Association of the Chemical Industry (VCI) – in cooperation with the trade unions and occupational safety organisations – further advanced the issue of occupational safety and health. In this context, the VCI and companies and authorities like the BAuA developed another code of conduct for the chemical industry to handle nano-materials in the workplace and guidelines for workplace safety involving nano-materials (BAuA & VCI 2007; VCI 2006).

In 2011 the second NanoKommission of the Federal Government published and presented its final report and the working group reports in a public discussion (NanoKommission 2011). Furthermore the State Committee of Experts on the Environment analysed envi-

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<sup>17</sup> See also printed matter (Drucksache 16/6337 2007) of the German Parliament.

ronmental implications of nanotechnology in a special report (Drucksache 17/7332 2011).

Further topics of the German regulatory discourses after 2010 included questions like environmental and health protection, a nano-product register, whose feasibility was analysed by the Ökoinstitut Freiburg in a study published in 2010 (Öko-Institut 2010). In the beginning of 2013 the Federal Departmental Research Establishments presented the initial review of their joint research strategy on health and environmental risks of nano-materials which simultaneously provided an outlook of further strategic alignment of nano-EHS-research (UBA et al. 2013).

In Switzerland, the regulatory discourses after 2006 almost exclusively focused on synthetic nano-materials. Thus the Federal Office for Environment (BAFU) and the Federal Office of Public Health (BAG) together with invited authors and coordinated by the Innovationsgesellschaft composed a basic report. This report covered issues like innovation potential, chances, environmental and health risks and the need for accompanying research, and dialogue (CH-BAFU & CH-BAG 2007). On the basis of this report the Swiss Government

(the Federal Council) adopted the action plan “*Synthetic Nano-Materials*” in 2008.

This action plan outlined the Swiss Government’s assessment that no additional regulation on legislative level was needed. However, the Government announced to make adjustments at the ordinance level. The report concluded with four recommendations: 1. communication and promotion of the public dialogue on benefits and risks of nanotechnology, 2. supporting scientific and methodological conditions for identifying and avoiding potential harmful effects on human health and the environment, 3. establishing regulatory conditions for a responsible development of nanotechnology, 4. A better use of existing funding instruments (CH-Bundesrat 2008).

In 2008 the Swiss National Science Foundation (SNF) launched a national research program ‘Opportunities and Risks of Nano-materials’ with a strong focus on hard science and toxicological research.<sup>18</sup> In 2008 the Swiss Academies of Arts and Sciences published a policy document on nanotechnology (Pohl & Nussbaum 2008). This paper

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<sup>18</sup> See: 22.10.2008: Tender of the national research program NFP 64 by the Swiss National Science Foundation (SNF) ([www.nfp64.ch](http://www.nfp64.ch), viewed 17.7.2012).

presented an inventory of nano-science and nanotechnology related ethical, legal and social implications (ELSI) as well as risk-, social science and cultural studies research in Switzerland (Rossini & Pohl 2009). Furthermore, this policy document recommended that research, independent from the private sector, risk and ELSI research need to be promoted as well as the proactive exchange between science and society.

Issues discussed in the Swiss Parliament covered the question of a need for statutory regulations, risk and accompanying research as well as the application of the precautionary principle, governmental activities to identify risks, occupational and product safety, disposal and consumer information.<sup>19</sup>

Moreover, in the years 2011-2013, the responsible authorities in Switzerland developed a number of informal (soft law) measures such as the creation of a precautionary matrix, voluntary guidelines for industrial identification of nanotechnology-specific risks, and a

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<sup>19</sup> See e.g. Swiss National Council motion by National Councillor Maya Graf (gps) on the statutory regulation of nanotechnology and the launch of a national risk research program 11.05.2006 and postulate from then National Councillor Didier Burkhalter 13.06.2006, regarding the promotion of innovation (see [http://www.parlament.ch/D/Suche/Seiten/geschaefte.aspx?gesch\\_id=20114201](http://www.parlament.ch/D/Suche/Seiten/geschaefte.aspx?gesch_id=20114201) /visited 04.06.2014).



voluntary code of conduct for workplace safety, safety data sheets, guidelines for disposal, recycling and labelling, and a dialogue platform on consumer information on synthetic nano-materials in products and the info-nano-website.<sup>20</sup> In particular, Switzerland introduced a 'registration and product register for chemicals and nano-materials' in 2012 (BAG & BAFU 2013). Since then, the registration and notification of nano-materials requires additional information with regard to their identity, particle size, shape and composition. Regarding cosmetics, Switzerland has planned to harmonize its cosmetic law with that of the EU in 2015. Meanwhile nano-materials in cosmetics can be declared on a voluntary basis.<sup>21</sup>

Also self-regulatory initiatives were developed in Switzerland in the years 2005–2008. Thus, the Innovationsgesellschaft, a private consulting company with focus on risk management and safety issues of nano-materials, together with additional partners such as TÜV Süd and Interessengemeinschaft Detailhandel Schweiz, established the platform "Nano-Regulation" in 2005, the certifiable risk manage-

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<sup>20</sup> See <http://www.bag.admin.ch/nanotechnologie/12167/12168/index.html?lang=de> and <http://www.bag.admin.ch/nanotechnologie/12171/index.html?lang=de> (visited 04.06.2014).

ment and monitoring system CENARIOS and a principles-based code of conduct in 2007, all with a focus on nano-materials.<sup>22</sup> In the 2007 code of conduct the Swiss retail trade interest association declared that the signing members would act self-responsible, ask for nano-material related information within the supply chain and provide transparent information to the consumers (IG DHS 2007). In the same year the International Risk Governance Council IRGC, located in Geneva, developed a *Risk Governance Framework* for nanotechnology (IRGC 2006). This framework consisted of a conceptual scheme to analyse nanotechnology regarding international regulatory and science policy aspects with the aim to support the risk management for decision makers. This scheme particularly covered general aspects and visions of future generation nano-materials that lead to a rather broad and vague governance approach (ibid.).

In Austria the BMVIT engaged the ITA with the project NanoTrust in 2007, with the aim to detect knowledge gaps and potential regula-

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<sup>21</sup> See also (CH-BAG 2011; CH-BAG & Stiftung Risiko-Dialog 2010) and <http://www.bag.admin.ch/nanotechnologie/index.html?lang=de>, viewed 21.11.2013).

<sup>22</sup> See <http://innovationsgesellschaft.ch/> (visited 28.11.13).

tory deficits and to offer a discussion platform.<sup>23</sup> At the same time parliamentary initiatives and debates emerged. They covered issues such as regulation, occupational safety and health, health and environment, food, cosmetics, labelling, precaution and cosmetics.<sup>24</sup> In 2009 the Federal Ministry of the Environment (BMLFUW) established a platform, on which stakeholders and representatives from the administration, NGOs, and science met on a regular basis. In 2010 the Austrian Government adopted the Austrian Nanotechnology Action Plan (ÖNAP), prepared by working groups from the BMLFUW nanotechnology platform. The ÖNAP identified the three strategic fields environment, health and occupational safety, for governmental activity. The ÖNAP further provided recommendations on the review and the securing of the legal framework and worked out the legal situation in Austria and the EU. This particularly concerned the field of occupational safety and consumer protection. Furthermore the ÖNAP recommended to examine whether a

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<sup>23</sup> <http://nanotrust.ac.at>.

<sup>24</sup> For this and further references see Eisenberger, Nentwich, Fiedeler, Gázsó & Simkó (2011) 'Nano Regulation in Austria (I): Chemical and Product Safety', in ITA (ed), NanoTrust-Dossiers (Wien: Institut für Technikfolgen-Abschätzung (ITA), <http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier018en.pdf>).

nano-labelling or a nano-register would be needed and to launch, if necessary, a corresponding initiative on the EU level. Other recommendations consisted of coordinating with international legal developments (REACH, definition, standardisation) and promoted voluntary measures to strengthening the precautionary and polluter-pays principle. Furthermore, establishing a NanoInformationsPlatform (NIP) was scheduled to enable the exchange of information on nano-governance and regulation within the administration and with the public (NIP went on-line in late 2012).<sup>25</sup>

Thus, in Austria in 2010 the issues environment, research, economy and health dominated the regulatory discourses. Further governmental activities concerned mainly the participation in the regulatory processes at the EU level, the monitoring of the Austrian market, in particular of consumer products, but no concrete regulatory action (Kurath, et al. 2014). After the implementation of the ÖNAP EHS research was promoted to some extent.<sup>26</sup> The TA project NanoTrust has constantly been active in feeding the ongoing debates and was

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<sup>25</sup> <http://nanoinformation.at>.

<sup>26</sup> [www.ffg.at/nano-environment-health-and-safety](http://www.ffg.at/nano-environment-health-and-safety).

prolonged twice (in 2010 and 2013). It is now as a project funded not only by BMVIT, but also by three other federal ministries<sup>27</sup>. In 2013 the informal working party coordinating the NIP became institutionalised as the Austrian “Nano-Information-Kommission”, managed by the Federal Ministry of Health, and chaired by an ITA researcher.

Furthermore, the authorities of German speaking countries responsible for labour protection, environment protection, health protection, consumer protection etc. formed networks in a more formalised structure. Thus, the annual International Nano Authorities Dialogue (Nano-Behördendialog) was established, where representatives of the protective authorities of Austria, Switzerland, Germany and Liechtenstein – as a rule in the presence of guests from science, economy, and NGOs – exchange views on current developments and regulatory perspectives in nanotechnology.

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<sup>27</sup> Namely the federal ministries for the environment, for health, and for consumer protection.

At the EU level,<sup>28</sup> discourse intensified after the Commission issued the First Implementation Report 2005–2007 on the action plan (Commission 2007). Therein public health, safety, environmental and consumer protection issues were the main regulatory targets. Nevertheless, the Commission held the existing legislative framework, in principle, as suitable and adequate. One year later, in 2008 the Commission published a communication on regulatory aspects of nano-materials (COM 2008b). This communication still argued that in general, the existing legal framework covers hazardous implications and risks emerging from the use of nano-materials. Parallel to these activities however, the Commission adopted the first nano-specific legal act, a non-binding recommendation on a code of conduct for responsible nanosciences and nanotechnologies research, consisting of principles and guidelines for member states, public and private actors involved and interested in nanotechnology

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<sup>28</sup> For the developments up to 2010, further analysis and references see Eisenberger, Nentwich, Fiedeler, Gázsó & Simkó (2010) 'Nano Regulation in the European Union', in ITA (ed), NanoTrust-Dossiers (Wien: Institut für Technikfolgen-Abschätzung (ITA), <http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017en.pdf>).

research (COM 2008a).<sup>29</sup> Furthermore, the Commission also established a stakeholder dialogue (“Safety for Success”).<sup>30</sup>

Up to 2009 the discourse was as good as monopolized by the European Commission and the prevailing argument was that the legislative framework was adequate for governing nanotechnologies. A turning point however, was the Resolution of the European Parliament on regulatory aspects of nanomaterials (P6\_TA 2009) in answer to the Commission’s communication on regulatory aspects of nanomaterials (COM 2008a). With the resolution the Parliament partly took over thematic leadership from the Commission. In its resolution, the Parliament challenged the assessment of the EU Commission concerning the adequacy of the existing legal framework and demanded comprehensive legal steps to adapt the existing regulation to new nano-materials. The Parliament particularly con-

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<sup>29</sup> For a further analysis of the code of conduct see e.g. Vöneky/von Achenbach, Erste Stellungnahme zu der „Empfehlung der Kommission für einen Verhaltenskodex für verantwortungsvolle Forschung im Bereich der Nanowissenschaften und -technologien“, in: Vöneky (Hrsg), Informationspapiere der Max-Planck-Forschungsgruppe „Demokratische Legitimation ethischer Entscheidungen“ 6-2008; Bochon, Evaluation of the European Commission Recommendation for a Code of Conduct for Responsible Nanosciences and Nanotechnology Research, *Nanotechnology Law & Business* 2011, 117; Eisenberger/Nentwich, ‘The EU code of conduct for nanosciences and nanotechnologies research’, in ITA (ed), *NanoTrust-Dossiers* (Wien: Institut für Technikfolgen-Abschätzung (ITA), <http://epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier036en.pdf>).

<sup>30</sup> For the first of four organized dialogues between 2007 and 2011 see [http://ec.europa.eu/health/nanotechnology/events/ev\\_20071025\\_en.htm](http://ec.europa.eu/health/nanotechnology/events/ev_20071025_en.htm).

firmed the principle “no data, no market”, developed within the context of the European chemicals regulation REACH,<sup>31</sup> and insisted on its enforcement also in the field of nano-materials. The Parliament also requested political and institutional reactions such as the establishment of a “nanotechnology coordinator”, to link the policies of the various Directorates General.<sup>32</sup>

In 2009 the Commission issued the Second Implementation Report (Commission 2009). At this point the Commission acknowledged that some areas of legislation would need adaptation. The Commission referred to chemicals, novel food, food additives and cosmetics as main areas of regulatory interest. Important advisory functions were taken over by the European Group on Ethics in Science and New Technologies (EGE)<sup>33</sup> and by Scientific Committees (see in particular Scientific Committee on Emerging and Newly Identified Health Risks – SCENHIR and Scientific Committee on Consumer Products – SCCP)<sup>34</sup> as well as European agencies (such as European

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<sup>31</sup> Regulation EC 1907/2006.

<sup>32</sup> For further analysis of the European Parliament Resolution see (Eisenberger, et al. 2010).

<sup>33</sup> See in particular opinion n 21 – 17/01/2007 – Ethical aspects of nanomedicine.

<sup>34</sup> See e.g. SCENIHR, Opinion on: Risk Assessment of Products of nanotechnologies,



Chemicals Agency – ECHA or the European Food Safety Authority – EFSA) who composed various reports on nanomaterials (e.g. ECHA 2012; EFSA 2012). In 2010, the STOA panel of the European Parliament launched a separate TA study on NanoSafety.<sup>35</sup> In addition various research groups, funded by the EU, started analysing nanotechnology regulation (e.g. NanoCode)<sup>36</sup>.

From 2009 onwards the regulatory discourse in the EU was mainly dominated by the Commission and the Parliament and focused on regulatory issues of nano-materials. The discourses involved further EU institutions, like the EU Council and the European Economic and Social Committee,<sup>37</sup> although their role was minor.

Partly in response to the European Parliament Resolution (P6\_TA 2009) the European Union started to develop nano-specific provi-

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adopted on 19 January 2009; Opinion on: The scientific aspects of the existing and proposed definitions relating to products of nanoscience and nanotechnologies, adopted on 29 November 2007; Opinion on: The Appropriateness of the Risk Assessment methodology in accordance with the technical guidance documents for new and existing substances for assessing the risks of nanomaterials, adopted on 21-22 June 2007; Opinion on: The appropriateness of existing methodologies to assess the potential risks associated with engineered and adventitious products of nanotechnologies, adopted on 10 March 2006; SCCP, Opinion on: Safety of Nanomaterials in cosmetic products, adopted on 18 December 2007.

<sup>35</sup> [www.europarl.europa.eu/stoa/cms/studies](http://www.europarl.europa.eu/stoa/cms/studies) (visited 13.08.2013).

<sup>36</sup> <http://www.nanocode.eu>.

<sup>37</sup> For further references see (Eisenberger, et al. 2010).

sions basically from 2009 onwards.<sup>38</sup> These regulatory efforts so far primarily concerned food,<sup>39</sup> cosmetics<sup>40</sup> and chemicals<sup>41, 42</sup> The nano-specific provisions within these regulations follow a similar model: The regulations regularly define nano-materials and contain notification and labelling requirements.<sup>43</sup> In chemicals regulation nano-specific adjustments (REACH regulation and CLP regulation) have been discussed in detail, negotiated, but so far only implementations on application-level have been conducted.<sup>44</sup>

In addition to these hard law efforts the European Commission adopted a further non-binding recommendation on the definition of nano-materials.<sup>45</sup>

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<sup>38</sup> Nano-specific provision can already be found in EC 1333/2008 (food additives). Art 12 states the following: „When a food additive is already included in a Community list and there is a significant change in its production methods or in the starting materials used, or there is a change in particle size, for example through nanotechnology, the food additive prepared by those new methods or materials shall be considered as a different additive and a new entry in the Community lists or a change in the specifications shall be required before it can be placed on the market.“

<sup>39</sup> Regulation EU 1169/2011 (food information).

<sup>40</sup> Regulation EC 1223/2009 (chemicals).

<sup>41</sup> Regulation EU 528/2012 (biocidal products).

<sup>42</sup> For the early developments up to 2010 with further references see e.g. (Eisenberger, et al. 2010). For labelling requirements see e.g. (Eisenberger, et al. 2013). See also the directives on electrical and electronic equipment (Directive EU 2011/65) and on waste electrical and electronic equipment (Directive EU 2012/19).

<sup>43</sup> For further analysis and references see (Eisenberger, et al. 2013).and the proposal for a Regulation on medical devices COM(2012)542.

<sup>44</sup> For further references, see e.g. (Eisenberger, et al. 2010) and [http://echa.europa.eu/view-article/-/journal\\_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated](http://echa.europa.eu/view-article/-/journal_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated).

<sup>45</sup> 2011/696/EU.

The following section discusses how the constellations of the most prominent actors, issues and practices in the discourses of the three analysed countries and the EU have shifted over the three phases.

### **3. Issues, actors and practices of the three phases**

#### ***3.1. Issues: From nanotechnology to nano-material and from ELSI to EHS***

The *early phase* (2000–2005) was characterised by a broad thematic scope in the negotiations of nano-sciences and nanotechnologies in Germany, Switzerland and at the EU level. Those discourses comprised issues like its economic potential, promotion of innovation, research policy, sustainability, nano-materials, nano-phenomena, visions, but also potential implications. The discourse on implications initially covered more general and higher-level areas such as ethical, legal and social implications (ELSI). During the *middle phase* the issues discussed shifted in all the analysed places in two respects; first, a shift from nanotechnology to nano-materials and second a shift in accompanying research from ethical, legal and social implications (ELSI) to environmental health and safety issues (EHS) oc-

curred. The *late phase* was characterized by a comprehensive and stabilized thematic focus on nano-materials, used in consumer products and specific related (EHS) regulatory issues, like precaution as well as questions of definition and nomenclature. More broadly scoped and visionary issues discussed in early TA studies and public debates, such as human enhancement and nano-medicine, became less important in the late phase.

### ***3.2 Actors: Expanding the range from political institutions to non-governmental and commercial organisations***

The spectrum of the actors involved in the discourses expanded throughout the three phases and shifted from political institutions traditionally involved in regulatory issues to various societal and non-governmental actors. The regulatory discourses in the *early phase* was particularly characterised by activities of the related authorities, members of parliament, TA organisations and actors of the private sector such as chemical companies and their industry association in Germany; respectively reinsurance companies, advisors and think tanks in Switzerland. In the *middle phase* the spectrum of in-

volved authorities, parliamentary groups and organisations of the private sector widened. New actors such as NGOs and, in Germany, a national advisory board composed of the most important stakeholders, stepped on the stage. This led to a shift from actors, who framed foremost innovation- and technology issues towards actors, focusing more on environment, health and safety related issues, like members of the related authorities and civil society organizations. This shift further accentuated in the *late phase*, in which additional actors, specialised in issues, like nano-materials, environment, health and safety issues, like consumer organizations entered the discourse. The analysis of the actors involved throughout the three phases showed, that particularly actors representing non-governmental and commercial organisations gained in importance. Due to their openness for soft law and discursive regulatory approaches, they obtained increased influence in nano-related regulatory issues. In Germany, for example, the association VCI, the chemicals company BASF and the environmental association BUND actively participated in the early phase of the discourse and became members of the NanoKommission—the national dialogue committee that considera-

bly influenced German nanotechnology policies. This enabled such actors to integrate their objectives, interests and intentions at the core of political decision making.

Discourses on legally binding and hard law measures, like the proposed amendments to the EU chemicals legislation REACH and the idea to implement reporting and communication tools on a mandatory level, showed a profound gap in the interests and positions of the various stakeholder groups. Therefore both, *within* nation-states with distinct stakeholder differences for national regulation as well as *between* nation-states with different economic and political preference structures for a European regulation, political consensus could not have been obtained so far.

### ***3.3 Practices: ‘Governance turn’ or ‘Hard law shift’?***

Our analysis of the regulatory discourse on nanotechnology showed that in particular self-regulatory and soft law practices played an important role, such as assessment studies, action plans, safety recommendations, guidelines, precautionary matrix and research-policy papers, cooperative forms of communication and negotiation like

stakeholder dialogues and dialogue platforms, as well as codes of conduct, product guidelines and certification systems. In contrast to modes of governance based on traditional statutory regulations, these new governance forms dominated the discourse throughout all phases and gained in importance over the time in all the analysed countries.<sup>46</sup> The EU, however, between 2004 and 2009 followed an approach which tried to foster the adoption of soft law measures (such as the EC CoC). Due to some pressing initiatives of the European Parliament the EU started to implement nano-specific provisions (e.g. cosmetics, food labelling, biocidal products). In this regard at the EU level there is a coexistence of two different approaches (a mix of soft and hard law), though EU law in this field seems to go (slowly) towards a more detailed regulation on several domains and sectors.

However, with regard to more formalized steering approaches and schemes, like codes of conduct, guidelines and monitoring instruments, the countries showed some differences. While such forms haven't been developed in Austria so far, their individual shapes and

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<sup>46</sup> This is particularly applicable at state level (cf. Fiedeler, et al. 2010).

the actors involved considerably differed in Germany and Switzerland. In Germany, mainly manufacturers in cooperation with associations and authorities developed such schemes (BASF, VCI, BAuA), while this happened in Switzerland mainly by think tanks and tertiary sector firms, like re-insurance and consulting firms, the latter also and in cooperation with authorities (IG-DHS, Innovationsgesellschaft, IRGC and SwissRe).

#### **4 Two regulatory cultures in governing nanotechnology**

The analysis of the regulatory discourse on nanotechnology in Germany, Austria, Switzerland and the EU showed that the discussed issues, the involved actors and the observed practices corresponded in many respects. This might be due to the strong link of the three countries with the EU in various regulatory fields related to nanotechnology. However, the comparison of the thematic focus in the analysed cases showed two different governance approaches: On the national level, besides the classical, visionary and innovation-driven discourses, technology assessment was an early issue in all the three analysed countries. TA issues were followed by a general and over-



all focus on substance *risks* respectively on potentially adverse implications of nano-materials, mainly in consumer products. Furthermore, all the three countries showed governance approaches based on soft law, self regulation and forms of new governance. None of the analysed countries however, used such based on hard law.

At the EU level in contrast, also statutory regulation was used and the regulatory discourse focused both, products and risks. Until 2009 the EU governance approach was oriented to use and adapt the existing regulation and used soft law to foster the self-regulatory capacities of mainly private actors (like e.g. COM 2008a). After 2009 selective acts have been adopted to nano-materials (e.g. cosmetics, biocidal products, food), which stand for a product-oriented approach. In this sense, the EU Commission prioritizes the general regulatory framework or the *incremental approach*, which provides for an ongoing and case specific introduction and implementation of nanotechnology related issues in the existing legal framework against the idea of establishing an entirely new regulatory framework for nano-materials (Fleischer, et al. 2012).

In addition to adapting the existing legal framework, the European Commission also introduced modes of governance based on more informal instruments of soft law nature. While the modes of governance based on statutory law (or the hard law measures) focused nanotechnology *products* and developments, such as cosmetics, food and biocides, the soft law measures and the new modes of governance mainly concentrated on *risks*. This was the case with the EU CoC as well as with the recommendation on a definition of nanomaterials.

In addition to the *risk-based* orientation within the nation states, the regulatory culture of the EU is here characterized as *risk-based and product-oriented*. Therefore, while governance measures in the individual countries primarily focused on potentially hazardous implications, respectively *risks*, those on the EU level also focused *products*. Those two approaches cannot clearly be distinguished from each other, rather they are intertwined and aspects of both can be found in all the analysed countries. In this notion, ‘regulatory cultures’ are not stable entities as the boundaries between the various political spaces are vague and overlapping. This is particularly the

case for Germany and Austria as EU members, but also for the non-member Switzerland. As a conclusion this study argues that risk based regulatory culture approaches could have been observed in all the analysed countries (Germany, Austria and Switzerland) as well as on the EU level. A product oriented regulatory culture approach, however, has only been observed on the EU level.

Beside these more general, issue-focused cultural characteristics of the regulatory discourse in the analysed countries and at the EU level, this study points to different *strategic approaches*, regarding the actors involved and the regulatory practices. The risk orientation implies a focus not only on predictable and scientifically measurable implications but also on hypothetical, unclear, uncertain and imprecise aspects, which on the country level opened up a wide range of soft law and self-regulatory approaches. Thus, the analysed countries showed different nation-specific approaches and strategies in the thematic and formal treatment of nanotechnology, each linked to local political cultures:

In *Germany*, among the various involved actors, particularly manufacturers, federal authorities and the national dialogue committee

NanoKommission played prominent roles. Manufacturing companies and associations developed self-regulatory instruments at a relatively early stage also in cooperation with authorities. These activities might have an important impact on the consensual and cooperatively oriented German culture in governing nanotechnology. Federal authorities were involved in such activities as well as in assessment studies and in national and international collaborations. The NanoKommission was particularly important in framing the overall consensus-based atmosphere in the German nanotechnology discourse, despite observable differences between the innovation-oriented actor groups and those primarily standing for protective aims. Thus, in Germany the involvement of various stakeholder groups constituted an important emphasis and was institutionalised at the highest political level.

Therefore, the leading strategy in the German nanotechnology discourse can be characterized as *cooperative and self-regulatory*. This approach might have its roots in a strong tradition of a neo-corporatist culture in the governance of science and technology and substance-related risks (e.g. Daemmrich 2004; Jasanoff 2005;

Schreurs 2002). However, this culture might be constantly challenged by the divergent claims and expectations of stakeholders to a formal legislation of nano-materials and nano-products.

In *Austria* the regulatory discourse began later than in the other observed places and mainly reacted to international activities. Here, particularly TA played an important role within the regulatory discourse. In the context of the national action plan almost all interested actors were incorporated, what could also be explained by the neo-corporatist regulatory culture, also observable in the Austrian context. In particular the implementation of the Nano-Information-Plattform constituted a cooperative procedure in which not only authorities and agencies but also industry, social partners and NGOs were included. However, the discourse was particularly dominated by authorities with support by TA and other interested actors. Self-regulatory and cooperative governance approaches by non governmental actors, like manufacturers, have not been observed in Austria. Therefore, the Austrian strategic orientation can also be classified as *cooperative*, however, not as self-regulatory as it is the case in Germany.

In *Switzerland*, in contrast to the other analysed places the regulatory discourse, particularly in the early and middle phases, was characterised by the absence of authorities and manufacturing companies. Similar to Germany, members of parliament but in contrast to the German manufacturers, tertiary sector companies were important. They composed assessment reports and established self-regulatory approaches, like monitoring systems and risk management schemes *for* the manufacturers. Only the last phase was characterised by a takeover of thematic leadership by the authorities. The related authorities issued an action plan, primarily focusing on opportunities and risks, the need for research and dialogue, contributed to initiating a national research program funding EHS research and issued a precautionary matrix and recommendations for workplace safety. This might have been a reaction to international and supranational activities, parliamentary inquiries and activities of non-governmental actors. Thus, also the Swiss regulatory discourses showed a *self-regulatory* orientation.

Compared to the other two countries, however, the regulatory discourse in Switzerland, despite its basic-democratically oriented

regulatory culture, did not show a distinct focus on participation, consensus and cooperation. Rather a wait-and-see strategy of governmental actors could be observed, which initially, with the exception of the national TA organization, left nanotechnology governance basically to non-governmental actors. Those, similar to Germany, but with different actor constellations, established self-regulatory approaches. In the late phase, these were taken up by the authorities, which developed soft law approaches. Therefore the strategic orientation of the risk-based regulatory culture in Switzerland can be described as *self-regulatory* and *soft law oriented*.

*European Union:* Up to the EU Parliament resolution on regulatory aspects the EU mainly used a risk-based culture in governing nanotechnology by focusing on non-binding, informal governance approaches (a strategy, an action plan, a recommendation for a code of conduct, a recommendation on definitions and a TA report). After 2009 the EU also used hard law governance and applied a product-oriented culture, focusing on some selective sectorial fields (like food, chemicals and cosmetics). In general, the regulatory discourse

took place within the institutional framework, laid down in the EU treaties.



	EU	Germany	Austria	Switzerland
regulatory culture	product based/ risk based	risk based		
strategic characteristics	hard law/ informal	cooperative/ self-regulatory	cooperative	self-regulatory/ informal

Table 1: Two regulatory cultures and their strategic characteristics on supranational and national level

Hence, these two regulatory cultures led to different regulatory outcomes: At the level of the nation states informal strategic orientations, such as cooperative and participative approaches, including stakeholder groups in the regulatory discourse were important in Germany and Austria. Furthermore, self-regulatory approaches were developed by authorities; in Germany often in cooperation with manufacturers and in Switzerland mainly after such were developed by tertiary sector companies. This is not to say that hard law will be replaced by these soft law measures and new governance in the future but governance modes based on soft law, self-regulation and new governance framed the regulatory discourse in the analysed countries to a considerable extent.

Modes of governance based on hard law have only been used at the EU level. In this context, the hard law discourse in the two member

countries Germany and Austria was to a great extent delegated to the supranational level.

The high degree of convergence in the regulatory cultures of Germany and Austria is surprising as the constitutional framework would suggest wider difference. While the rights-based Austrian constitution which is oriented to fundamental rights, is basically permitting research as long as it is not forbidden.<sup>47</sup> In contrast, the value based German constitution requires governmental authorisation for hazardous technologies<sup>48</sup>.

Why this genuine regulatory difference hasn't manifested itself more profoundly in the analysed discourses might be due to the various elements shaping the regulatory discourse in the analysed countries. In this context, the influence of the constitution on subjacent regulatory levels produced to be more limited than intuitively presumed. Furthermore, EU law might have gained in importance compared to national constitutions. In addition, the individual actors involved in regulatory discourses on emerging technologies might have received

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<sup>47</sup> In this context see e.g. (Kopetzki 2011).

an increasingly dominant role in framing the used modes of governance.

The important role governance based on soft law and self-regulation played at the national level might have contributed to strengthening the influence of non-governmental actors in the regulatory discourse on emerging science and technology fields. However, as the genuine logics of external stakeholder groups significantly differ from those of institutions traditionally involved in the regulatory process, side aspects have gained importance within the regulatory discourse. Those concern issues, like bringing in own agenda, securing an own market, posing questions of power and increasing the influence in science policy and regulatory issues, like avoiding statutory regulation. These aspects not only distract from the genuine aim of environmental regulation, namely protecting public health and the environment, but might also contribute to regulatory uncertainty. Not least, this uncertainty conflicts another aim of science policy, namely the promotion of innovation.

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<sup>48</sup> In this context see the Constitutional Court's decision in the Kalkar case (BVerfG, decision 8. 8. 1978 - 2 BvL 8/77; OVG NRW (lexetius.com/1978,2)).

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